IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **WAVE 1 CASES ATTACHED ON EXHIBIT A**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION[1] TO EXCLUDE CERTAIN TESTIMONY OF TERESA IRWIN, M.D., PURSUANT TO FED. R. EVID. 702 AND *DAUBERT*

Plaintiffs, pursuant to Fed. R. Evid. 702 and *Daubert*,[2] submit this memorandum in support of Plaintiffs' motion to exclude certain opinions that Teresa Irwin, M.D., an expert for Defendants, set forth in her general expert report and in her deposition. In support of this motion, Plaintiffs say as follows:

GENERAL OPINIONS

Dr. Irwin's general report[3] contains a number of different opinions that exceed the scope of her qualifications. Dr. Irwin is a Gynecologist and is Board Certified in Female Pelvic Medicine and Reconstructive Surgery and Obstetrics and Gynecology.[4] In her general report, Dr. Irwin opines on a multitude of issues related to the design of the Gynecare TVT,[5] including

[1] In compliance with PTO No. 217, attached to this Motion as Exhibit A is a list of cases to which this Motion applies.
[2] *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).
[3] Teresa Irwin, MD, Report re: the Gynecare TVT Retropubic, dated February 29, 2016 (attached as Ex. B).
[4] Ex. B at p. 1.
[5] Ex. B at pp. 40-55.

pore size,[6] weave,[7] weight/density,[8] and absorption of mesh.[9] Dr. Irwin also opines on issues relating to the processing of allograft materials.[10] Dr. Irwin's opinions concerning these subjects are outside the scope of her education, training and experience and she is not qualified to testify on such matters.

LEGAL STANDARDS

The Court acts as gatekeeper to determine whether an expert's testimony is reliable and relevant.[11] This gatekeeping function applies not only to "scientific" testimony, but also to testimony based on "technical" and "other specialized" knowledge.[12] The proponent of expert opinion bears the burden of establishing its admissibility.[13] Where the proponent fails to establish all of the prerequisites of admissibility, the exclusion of expert testimony is within the court's sound discretion.[14] The admissibility of expert opinion testimony is governed by the Federal Rules of Evidence.[15] In a federal court sitting in diversity jurisdiction, the admissibility of expert testimony is a question of and controlled by federal law.[16] In multidistrict litigation, the law of the transferee circuit governs questions of federal law.[17]

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[6] Ex. B at p. 25.
[7] Ex. B at p. 25.
[8] Ex. B at pp. 25-26.
[9] Ex. B at p. 26.
[10] Ex. B at pp 27-29.
[11] *Daubert*, 509 U.S. at 598 (1993); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999); Fed. R. Evid. 702.
[12] *Kumho Tire Co., Ltd.*, 526 U.*S. at* 141.
[13] *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).
[14] *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142 (1997).
[15] *Daubert*, 509 U.S. at 587.
[16] *See, e.g., Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (*quoting Scott v. Sears, Roebuck & Co.*, 789 F.2d 1052, 1054 (4th Cir. 1986)); *Fraley v. Stoddard, D.P.M.*, 73 F. Supp. 2d 642, 646 (S.D. W.Va. 1999).
[17] *See, e.g., In re Temporomandibular Joint Implants Prod. Liab. Litig.*, 97 F.3d 1050, 1155 (8th Cir. 1996) (*citation omitted*), *aff'd*, 490 U.S. 122 (1989)); *In re Stucco Litig.*, 364 F. Supp. 2d 539, 540 (E.D.N.C. 2005) ("[i]n the context of this multidistrict case, the court must apply the law of the Fourth Circuit when analyzing questions of federal law").

The proponent of expert testimony must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible."[18] Expert testimony is admissible if the expert is proven to be qualified and said testimony (1) "will help the trier of fact to understand the evidence or to determine a fact in issue," (2) is "based upon sufficient facts or data," (3) is "the product of reliable principles and methods" and (4) has been reliably applied "to the facts of the case."[19] An expert's opinion is inadmissible unless the expert is qualified by virtue of knowledge, skill, experience, training or education," which is sufficiently related to the particular subjects at issue in the case.[20] In the context of Rule 702, knowledge "connotes more than subjective belief or unsupported speculation."[21] Trial courts must ensure that a purported expert witness "is not merely parroting the opinions of others, but that the *matters upon which she will opine are clearly within her area of expertise*."[22] One of the fundamental prerequisites of the admission of an expert's opinion is that it be related to that expert's specialized knowledge.[23]

ARGUMENT

A. Dr. Irwin is not qualified to provide opinions concerning the design of the Gynecare TVT mesh.

Dr. Irwin admits that she is not a design expert,[24] does not have a degree in design of medical devices, she has never designed a pelvic mesh product or consulted with a pelvic mesh

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[18] *Maryland Cas. Co. v. Therm–O–Disc, Inc.*, 137 F.3d 780, 783 (4th Cir.1998).
[19] Fed.R.Evid. 702.
[20] Fed. R. Evid. 702; *see, e.g.*, *Cooper v. Lab. Corp. of Am. Holdings, Inc.*, 150 F.3d 376, 380 (4th Cir. 1998); *Bombardiere v. Schlumberger Tech. Corp.*, 934 F. Supp. 2d 843, 846 (N.D. W. Va. 2013).
[21] *Daubert*, 509 U.S. at 590.
[22] *Bouygues Telecom, S.A. v. Tekelec*, 472 F. Supp. 722, 730 (E.D.N.C. 2007) (emphasis added).
[23] *See, e.g.*, *U.S. v. Johnson*, 54 F.3d 1150, 1157 (4th Cir. 1995).
[24] Deposition of Teresa Irwin, MD, 3/25/16 (general report) at 66:3-17 (excerpts attached as Ex. C).

manufacturer concerning the design of pelvic mesh.[25] She has never conducted any research in to the specifics of pelvic mesh design and never published any peer-reviewed articles concerning pelvic mesh design.[26] Dr. Irwin admits that she has never consulted with a mesh manufacturer concerning pore size of pelvic mesh and never published any peer-review articles concerning pore size of pelvic mesh.[27] She has never conducted any independent research of pore size of pelvic mesh outside her literature review for her opinions in these cases.[28] Dr. Irwin admits that she has never consulted with a mesh manufacturer concerning weave of pelvic mesh, never published any peer-review articles concerning weave of pelvic mesh and never conducted any independent research of weave of pelvic mesh outside her literature review.[29] Dr. Irwin admits that she has never consulted with a mesh manufacturer concerning density of pelvic mesh, never published any peer-review articles concerning density of pelvic mesh and never conducted any independent research of density of pelvic mesh outside her literature review.[30] Dr. Irwin concedes she has never conducted any testing relating to the weight or density of pelvic mesh.[31] Dr. Irwin admits that she has never consulted with a mesh manufacturer concerning absorption of pelvic mesh, never published any peer-review articles concerning absorption density of pelvic mesh and never conducted any independent research of absorption of pelvic mesh outside her literature review.[32] Dr. Irwin admits she does not have a degree in biocompatibility.[33] She has never consulted with a mesh manufacturer concerning biocompatibility or biomaterials, never published an article in peer-reviewed publications concerning biocompatibility or biomaterial

[25] Ex. C at 35:16 – 36:2, 66:3-17.
[26] Ex. C at 36:21 – 37:8.
[27] Ex. C at 37:24 – 38:11.
[28] Ex. C at 38:12 – 39:1.
[29] Ex. C at 39:15 – 40:1.
[30] Ex. C at 40:10 – 41:8.
[31] Ex. C at 41:17-19.
[32] Ex. C at 42:5 – 43:2.
[33] Ex. C at 43:14-17.

characteristics of pelvic mesh and never conducted any independent research concerning biocompatibility or biomaterial characteristics of pelvic mesh outside her literature review.[34] She has never examined any mesh products she has removed with anything other than her naked eye.[35] She has never conducted any testing on mesh that she has removed to determine whether there was any degradation of the mesh product.[36]

In addition to an entire section addressing the design of the Gynecare TVT and safety issues related, in part, to that design, Dr. Irwin's general report sets forth the following opinions:

> In order to achieve the best host response to the reconstructive materials, the following factors need to be optimized. For synthetic mesh, pore size (space between fibrils); weave (mono vs. multifilament); weight (or the density); and absorption (absorbable vs non absorbable) are the critical factors of the graft material.[37]
>
> In synthetic material, pore size and weave influences cellular infiltration, risk of infection, mesh density and flexibility [***89:*** *Iglesia 2007*]. In animal studies, macropores (>75 microns; 1 mm = 1000 microns) allow for host cell colonization with collagen deposition and angiogenesis. In-vivo studies show that this allows **un**restricted immune cell access, therefore reducing the infection risk.[38]
>
> Weight and elasticity are determined by pore size. Meshes with larger pores tend to be of a smaller weight and more elastic, versus the smaller-pored meshes which are of larger weight and less elastic. With larger pores, there is less material content and more flexibility rendered to the scar [***90:*** *Cobb 2006*]. This has led to the conclusion that lightweight materials have a lower rate of infection and/or erosion than heavier weighted graft materials. TRUE infection contributed by mesh is very, very low. One must keep in mind that the TVT width is only ONE centimeter, so very little material is implanted. There has been a movement toward lighter mesh in order to reduce the risk of infection, pain and erosion. However, this is primarily in the arena of prolapse and/or large hernia repairs, which require a larger amount of mesh material. This does not carry the same benefits directly for a small piece used for incontinence, which is treating a functional defect and NOT a large anatomical defect. Ethicon TVT weighs approximately 100 gm/m2 [***91***: *Moalli PA1. Tensile properties of five commonly used mid-urethral slings relative to the TVT. Int Uro gynecol J Pelvic Floor*

[34] Ex. C at 43:22 – 44:12; 44: 23 – 45:17.
[35] Ex. C at 131:5-22.
[36] Ex. C at 132:4-7.
[37] Ex. B at p. 25.
[38] Ex. B at p. 25.

Dysfunct. 2008 May;19(5):655-63], and has a pore size of 1379 microns (well above 75 microns, which is considered a macropore). There is a need for an optimal weight/density, such that if it is too light, then there is a loss in the efficacy of its intended function. Treating an anatomical problem versus a functional problem requires different specifications, as in the case of treating prolapse versus incontinence. An ultra- lightweight mesh may work well to improve the anatomic defect of prolapse, but would not accomplish improvement in the functional defect of incontinence. The latter is best accomplished by a lightweight mesh like the TVT mesh.[39]

Prolift (polypropylene) & Ultrapro are also highly studied mesh devices, which are lightweight at 45 gm/ m2, 2.5 mm pores & ultra-lightweight at 28 gm/ m2, respectively. Mesh exposure is the same for these non-absorbable and partially absorbable materials, however, as seen with Vypro, the dissolved portion caused local inflammation, higher recurrences and excess contraction [***106***]. It would not work well to use Prolift/ Ultrapro mesh material in TVT or other MUS, just because it is lightweight, as it will probably not be durable. Ethicon conducted a study for the use of Ultrapro in a stress urinary incontinence sling and found this partially absorbable mesh, would not be feasible because it stuck to the sheaths in a cadaveric study [***99****: ETH.MESH.09922570 - TVTO PA (TOPA) RD Memo on PA Mesh Assessments for TVTO-PA - Katrin Elbert Dec 12_2012.pdf*]. If there are only 3 pores across, this is probably not enough support that is required as the backboard of the urethra for urinary continence. Treating an anatomical problem versus a functional problem requires different specifications.[40]

The design of the TVT is universally accepted by the large academic bodies: ACOG, AUGS, AUA, EUA, ICS, IUGA, NICE and SUFU.[41]

The design of the TVT makes sense to the pelvic surgeon, as the TVT is placed in an area of the pelvis that the surgeon is an expert in operating upon, and has a physiologic-scientific basis. This is supported by the fact that it is placed in the midurethral position, the site that most frequently is known to develop weakness, which has a vitally important function in the maintenance of continence. In addition, to the public and to the patient, the design also makes sense.[42]

All of the data presented thus far (with more discussed below), further exemplifies the utility of the device as being very high, which is critically important. The utility of the TVT has been demonstrated in its ease of use, low morbidity, reproducibility, adaptability and efficacy. The procedure is reproducible by pelvic surgeons, can be done under multiple anesthesia modes

[39] Ex. B at p. 25.
[40] Ex. B at p. 27.
[41] Ex. B at p. 40.
[42] Ex. B at p. 41.

(including general, regional and even local anesthesia), as well as a "stand alone" procedure or in conjunction with other surgical procedures.[43]

The mesh used in the TVT is state of the art in design. It is macroporous (>75 microns) and monofilament, and the macroporosity for an only 1.1-cm-wide strip of mesh promotes mechanical anchorage with neovascularization and collagen formation [***98**: Amid 1997*].[44]

The design of the sheaths that cover the TVT mesh during implantation allows for smooth placement. The sheathes carry the load of passage and avoid any distortion of the mesh, they protect the mesh during placement and prevent any detensioning of the sling, they reduce the risk of infection, they allow the placement of the sling to be optimized, they allow for repositioning the tape prior to sheath removal, the sheathes are removable and they are non-reactive.[45]

The design of the TVT optimizes safety by using a single, very small vaginal incision about 1.5 to 2 cm, and avoiding the large abdominal incision needed for the BRU and AFS procedures. The Burch procedure, on the other hand, involves a 5-6 inch abdominal incision and a pubovaginal fascial sling that has multiple incisions (a large abdominal incision as well as a vaginal incision to pull the sling up into place). If fascia lata is used rather than rectus fascia, another incision in the leg is needed to harvest the fascia lata.[46]

The TVT's trocars curve outward and have a blunter tip so that they pass through tissues smoothly. These trocars are quite similar to the instruments used in the PFS, i.e. Stamey needles.[47]

Dyspareunia is rare following implantation of the TVT. The design of the TVT places the mesh under the midurethra via the small proximal anterior wall incision. It is located at a part of the vaginal wall, where forces and stress from penile contact are minimal. In addition, the design of TVT then provides for the mesh sling to traverse up (vertically) and away from the vagina.[48]

The macroporous mesh is state of the art, being >75 microns and monofilament. The Amid study of 1997 showed that this macroporosity allows for entry of fibroblasts, macrophages, blood vessels and collagen fibers, for tissue generation and reduction in the risk of infection [98: Amid 1997].[49]

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[43] Ex. B at p. 41.
[44] Ex. B at p. 42.
[45] Ex. B at p. 43.
[46] Ex. B at p. 45.
[47] Ex. B at p. 45.
[48] Ex. B at p. 46.
[49] Ex. B at p. 46.

> Other trocars have larger, pointed tips, with a greater risk of vessel or organ perforation. However, even small, thin trocars have a risk of perforation, due to the fact that tactile feedback is reduced, making organ perforation somewhat more likely, especially in less-experienced hands.[50]
>
> Many prior slings have not had, or do not have protective sheaths. This can lead to the "dragging effect" and possible tissue trauma. In addition, without the protective sheaths, there is a risk of too much stretching of the mesh, leading to suboptimal efficacy and/or too much tension.[51]
>
> TVT mesh is macroporous, allowing for collagen and inflammatory cells to enter for the purposes of neovascularization and as a protective mechanism. Microporous mesh, will not allow for WBCs to enter and assist in fighting infection, while allowing only the smaller sized bacteria to enter.[52]
>
> The design factors have shown it to be a very reasonable procedure and as the standard of care for which pelvic surgeons expect.[53]

Dr. Irwin's qualifications as a physician, even a physician specializing in pelvic floor surgery, are not sufficient to allow her to testify on design issues set forth above. In *Tyree v. Boston Scientific Corp.*,[54] this Court excluded opinions by Dr. Jerry G. Blaivas, one of the plaintiff's experts, relating to the design of pelvic mesh products. The Court ruled:

> Dr. Blaivas's experience removing SUI devices and observing complications during the removal process does not alone render him qualified to opine as to design. Dr. Blaivas worked in developing the autologous rectus fascial sling operation. However, this experience in developing procedures does not make him an expert in the design of a medical device. (See Blaivas Report [Docket 239–1], at 1–2). As a result, Dr. Blaivas lacks the "knowledge, skill, experience, training, or education" as to product design that Federal Rule of Evidence 702 requires. Fed.R.Evid. 702.[55]

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[50] Ex. B at p. 49.
[51] Ex. B at p. 49.
[52] Ex. B at p. 49.
[53] Ex. B at p. 51.
[54] 2104 WL 5320566 (S.D.W. Va. 2014).
[55] *Tyree*, 2104 WL 5320566 at *47.

In *Huskey v. Ethicon*,[56] this Court excluded the testimony of Dr. Michael Greenburg, a board certified toxicologist, relating the biocompatibility and mesh degradation. Dr. Greenberg had never testified about those subjects and admitted he was not a biomaterials expert.[57]

Dr. Irwin's qualifications and experience to not rise to the same level as similar physicians that this Court has found were qualified to testify about design and biocompatibility issues. In *Wise v. C.R. Bard, Inc.*,[58] this Court rejected the plaintiff's challenge to Dr. Marshall Austin, who specialized in gynecologic surgical pathology and cytopathology and examined 15-20 specimens per month, including specimens involving pelvic mesh products. This Court rejected the challenge to his qualifications and ruled:

> In addition to his extensive background in the field of gynecological pathology, where his experience ranges from publishing research to giving academic lectures, Dr. Austin has examined hundreds of vaginal mesh explants over the past ten years. (See generally Austin Report [Docket 203–1]). I find his qualifications sufficient to testify about the biocompatibility of mesh.[59]

Even though the Court determined that Dr. Austin was qualified to testify about biocompatibility, the Court excluded Dr. Austin's opinions on design and concluded:

> I agree with the plaintiffs that these opinions about the Avaulta's overall design go beyond Dr. Austin's expertise. While he has studied and observed the interaction between tissue and mesh products such that he can opine about biocompatibility, he has no demonstrated experience in designing or evaluating transvaginal products.[60]

On the other hand, the Court concluded that Dr. Donald R. Ostergard, one of the plaintiff's experts in *Tyree*, was qualified to testify about design issues due to his experience, including experience in the development of pelvic mesh products. The Court ruled:

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[56] 2014 WL 3362264 (S.D.W. Va. 2014).
[57] *Huskey*, 2014 WL 3362264 at *26-27.
[58] 2015 WL. 570070 (S.D.W. Va. 2015).
[59] *Wise*, 2015 WL. 570070 at *3.
[60] *Id.* at *4.

> After reviewing Dr. Ostergard's curriculum vitae, I conclude that Dr. Ostergard is qualified to provide opinion testimony on the design of polypropylene slings. He has performed countless pelvic reconstruction surgeries, instructed others on the performance of these surgeries, participated in the development of pelvic mesh devices, and authored several peer-reviewed articles on the safety and efficacy of polypropylene mesh products.[61]

While Dr. Irwin may be qualified to testify about specific causation issues relating to the Gynecare TVT mesh, she is not qualified to provide opinions concerning the design of the mesh or biocompatibility issues because she is not a design expert, has conducted no independent research on such issues and has never published on such issues. She does not have the necessary expertise required under Rule 702 or *Daubert*. Any such opinions, including the opinions specifically set forth above should be excluded.

B. Dr. Irwin's opinions that the Gynecare TVT was "state of the art" constitutes a legal conclusion.

Dr. Irwin opines on two separate occasions in her report that the Gynecare TVT mesh was "state of the art."[62] Dr. Irwin's conclusions that the TVT mesh is state of the art constitutes a legal standard/conclusion and should be excluded. In *Wise*, this Court excluded an opinion that the mesh product had no "inherent design defects" because the opinion "constitutes a legal conclusion that this court will not accept at trial."[63]

C. Dr. Irwin's opinions concerning mesh fraying are unreliable.

In her general report, Dr. Irwin opines:

> Some expert witnesses retained by plaintiffs in litigation may argue that mechanical cut mesh leads to fraying and loss of particles leading to pain.

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[61] *Tyree*, 2104 WL 5320566 at *36; *see also Wise v. C.R. Bard, Inc.*, 2015 WL 521202, *7 (S.D.W. Va. 2015)(finding Dr. Ostergard was qualified to testify about design issues).
[62] Ex. B at p. 42, 46.
[63] *Wise*, 2015 WL. 570070 at *4 (citing *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006)("[O]pinion testimony that state a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible").

> However, this has not been shown to occur. I have not seen any literature that discusses particle loss leading to pain, nor have I seen it in my practice.[64]

When questioned about this particular opinion, Dr. Irwin admitted she had not reviewed any internal Ethicon documents addressing fraying issues related to mechanically cut mesh. In particular, Dr. Irwin was unaware that Ethicon has known about fraying issues concerning mechanically cut mesh since 1998, including reports that particle loss was causing pelvic pain and dyspareunia.[65] She was not aware that Ethicon knew that fraying was "inherent in the design and construction of the product."[66] She was not aware that Ethicon knew that the very act of implanting mechanically cut mesh would cause elongation, narrowing of the mesh and small particles breaking off.[67] She was not aware that Ethicon knew that the removal of the sheaths on the mesh could cause fraying and particle loss.[68] She had not reviewed Ethicon company documents testing mechanically cut mesh and photographically documenting fraying, particle loss and degradation of the structure of the mesh.[69] After being shown the Ethicon company documents photographing the fraying issues, Dr. Irwin conceded "I guess I'd like to read a little more to make my opinions on this."[70]

Dr. Irwin's opinions concerning fraying issues related to mechanically cut mesh are unreliable and should be excluded. By her own admission, she needs to "read a little more" before providing any opinions on this issue.

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[64] Ex. B at p. 50.
[65] Ex. C at 80:19 – 82:16.
[66] Ex. C at 83:14 – 21.
[67] Ex. C at 84:22 – 85:7.
[68] Ex. C at 86:10 – 88:3.
[69] Ex. C at 88:8 – 89:24.
[70] Ex. C at 89:8-10.

CONCLUSION

Dr. Irwin may be qualified to provide specific causation opinions but she is not qualified to provide general causation opinions relating to the design of the TVT mesh product. Accordingly, her design opinions should be excluded. Her opinions concerning state of the art constitute a legal standard/conclusion and should be excluded. Her opinions concerning fraying issues related to mechanically cut mesh are unreliable and should be excluded.

This 21st day of April, 2016.

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CERTIFICATE OF SERVICE

I hereby certify that on April 21, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ P. Leigh O'Dell_____
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